

REMARKS:

Reconsideration of the rejections set forth in the Final Office Action mailed September 18, 2007 and entry of the present amendment is requested because Applicant respectfully submits that the Amendment places the application in condition for allowance or in better form for consideration on appeal. Claims 3, 4, 7, 8, 10, 11, 15-17, and 19-35 are currently pending.

In response to the Final Office Action, claims 3, 7, 17, and 20 have been amended, claims 1, 2, 5, 6, 12-14, and 18 have been canceled without prejudice (as directed to a nonelected group, which will be filed in a future divisional application), and new claims 24-35 have been added. No new matter has been introduced as the amendments are fully supported by the original disclosure, e.g., in paragraphs [0006] and [0056]-[0059], and in FIGS. 10-12B.

In the Final Office Action, claims 3, 4, and 15-17 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,607,444 (“the Lam reference”), claims 3, 4, and 15-17 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,632,762 (“the Myler reference”), and claims 3, 4, 7, 8, 10, 11, 15-17, and 19-23 were rejected under 35 U.S.C. § 102(b) as anticipated by either U.S. Patent No. 6,210,429 or U.S. Patent No. 6,325,826 (“the Vardi et al. reference”). Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning to the Lam reference, an ostial stent 20 is disclosed that includes a tubular body 24 and a flaring portion 25. Col. 5, lines 41-43. The stent 20 is delivered using a balloon catheter 23 that includes a balloon portion 37 and a tubular member 38 extending proximally

therefrom. Col. 6, lines 30-38. During use, the ostial stent 20 is positioned within the diseased portion 31 of a bifurcated vessel 21, whereupon the balloon catheter 23 is expanded such that the tubular body 24 is seated within and repairs the diseased vessel 21 and the flaring portion 25 is expanded and deformed so that the ostial stent 10 “caps” the ostium to the diseased portion 31 of the vessel 21. Col. 6, line 60 through col. 7, line 6. As can be clearly seen in FIGS. 6-8, the balloon 37 expands asymmetrically such that the balloon catheter 23 bends the flaring portion 25 of the stent 20 to an angle greater than ninety degrees, i.e., such that the flaring portion 25 is flared far beyond an angle perpendicular to a longitudinal axis of the stent.

Turning to the present claims, claim 3 recites a method of treating a secondary cardiovascular vessel extending from a primary cardiovascular vessel that includes providing a stent having distal and proximal stent portions, said proximal stent portion being more expandable than said distal stent portion; providing a balloon within said stent, said balloon having a distal balloon portion and a proximal balloon portion, said distal balloon portion being within said distal stent portion and said proximal balloon portion being within said proximal stent portion, said proximal balloon portion being more expandable than said distal balloon portion; positioning said stent so that said distal stent portion is located in the secondary vessel and said proximal stent portion is located in the primary vessel; and initially inflating said balloon, whereby said proximal balloon portion expands said proximal stent portion to form a flange engaging an interior wall of the primary vessel; and fully inflating said balloon whereby said distal balloon portion expands said distal stent portion to support the secondary vessel.

The Lam reference fails to disclose, teach, or suggest *initially* inflating a balloon,

whereby a proximal balloon portion expands a proximal stent portion to form a flange engaging an interior wall of the primary vessel, and then *fully* inflating said balloon whereby said distal balloon portion expands said distal stent portion to support the secondary vessel, as claimed.

Instead, the Lam reference discloses expanded balloon catheter 23, such that “the tubular body 24 is seated within and repairs the diseased vessel 21 *and* the flaring portion 25 is expanded and deformed so that the ostial stent 10 “caps” the ostium to the diseased portion 31 of the vessel 21.” Thus, the Lam reference teaches simultaneously expanding both the tubular body 24 and the flaring portion 25 simultaneously. Although the Lam reference makes a passing statement that it may be preferable that one follow the other, col. 7, lines 11-14, the Lam reference does not disclose, teach, or suggest how this could be accomplished. Accordingly, for these reasons, the Lam reference does not anticipate claim 3 and its dependent claims and does not otherwise render the claims obvious.

For similar reasons, independent claims 7, 19, 24, and 35, as well as their dependent claims, are also not anticipated by nor obvious over the Lam reference.

In addition to the reasons given above, claim 24 recites an expandable member that is initially inflated such that the proximal portion is inflated *and the distal portion is not fully inflated*, thereby flaring the proximal stent portion; and then fully inflating the expandable member to deploy the distal stent portion within the ostial branch. The Lam reference does not disclose, teach, or suggest such a method.

Further, claim 35 recites that the proximal portion of the expandable member has a *symmetrical bulbous shape* when fully expanded for flaring the proximal stent portion *up to a*

degree generally perpendicular to a longitudinal axis of the stent. The Lam reference fails to disclose, teach, or suggest such an expandable member. The Lam balloon is intended to expand into an asymmetrical shape that is not bulbous, as clearly shown in FIGS. 6-8. “Bulbous” means that the proximal portion is “bulb-shaped” or has a round, enlarged shape, as shown in FIG. 10 of the present application. (Also see, definitions of “bulbous” and “bulb,” e.g., at dictionary.com). The Lam balloon is clearly not bulb-shaped, but has an asymmetric hook shape, which is necessary to expand the flaring portion of the stent to an angle greater than ninety degrees.

In addition, several dependent claims recite additional features that are neither anticipated by nor obvious over the Lam reference. For example, claim 25 recites that the distal portion of the expandable member is partially inflated when the expandable member is initially inflated, while claim 26 recites that a distal end of the distal portion of the expandable member is inflated when the expandable member is initially inflated, thereby trapping plaque within the stent to prevent distal embolization. The Lam reference fails to disclose, teach, or suggest such an inflation procedure. As explained in paragraph [0059] of the present application, such an inflation sequence may trap plaque within the stent, preventing distal embolization. Thus, the recited inflation sequence may provide an enhanced safety feature not taught or suggested by the Lam reference. Similar sequences are recited in claims 33 and 34.

Turning to the Myler reference, this reference also does not disclose, teach, or suggest *initially* inflating a balloon or expandable member, whereby a proximal portion expands a proximal stent portion to form a flange engaging an interior wall of the primary vessel, and then *fully* inflating the balloon or expandable member whereby the distal portion expands the distal

stent portion to support the secondary vessel, as claimed. In contrast, in the method shown and described with reference to FIGS. 7 and 8 of the Myler reference, a stent has already been expanded to maintain patency of an artery when a balloon 24 is inflated to expand the proximal section 48 of the stent 44 into a flared configuration. Col. 6, lines 7-16.

Finally, turning to the Vardi et al. references (with reference to the Vardi et al. '826 patent's specification for simplicity), a branch stent 15 is disclosed that is disposed around a distal end of a branch catheter 25. Col. 7, lines 41-43. The contacting portion 18 of the branch stent 15 "is held in a collapsed position by a protective sheath 34, as shown in FIG. 6c." Col. 7, lines 45-47. The branch stent 15 is inserted over a branch guidewire 36 through an opening 16 of a main stent 12 and is "affixed in place by withdrawal of the protective sheath 34 (FIG. 6d) and insertion of the branch stent 15" until it contacts the perimeter of the opening 16. Col. 7, lines 50-56. Thus, the contacting portion 18 of the branch stent 15 (the only portion of the Vardi et al. stent that could arguably satisfy the claim language of the present claims) is not expanded by inflating a balloon or expandable member. Instead, the contacting portion 18 is self-expanding, i.e., is held in the collapsed position until the protective sheath 34 is withdrawn. The Vardi et al. reference does not disclose, teach, or suggest anything about flaring the contacting portion 18 by expanding a balloon, let alone teach or suggest initially inflating a balloon to flare the contacting portion and then fully inflating the balloon to expand the rest of the stent. Accordingly, the present claims are neither anticipated by or otherwise obvious over the Vardi et al. references.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Dated: March 7, 2008

Respectfully submitted,
VISTA IP LAW GROUP LLP

By


William A. English
Reg. No. 42,515
Attorneys for Applicant

2040 Main Street, 9th Floor
Irvine, CA 92614
Telephone: (714) 665-3953
Facsimile: (949) 625-8955